Exhibit M

From: Samir/Corporate/Torrent Ltd [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=USERDB8541DE]
Sent: 8/18/2018 9:10:13 AM
To: Jinesh Shah/Corporate/Plant/Torrent [jineshshah@torrentpharma.com]
CC: Sushil Jaiswal/Quality/Plant/Torrent [sushiljaiswal@torrentpharma.com]
Subject: Re: Fwd: Valsartan recall discussion needed

c type issue in europe etc?

From: Jinesh Shah/Operations/Plant/Torrent
To: Samir/Corporate/Torrent Ltd@TorrentPharma
Cc: Sushil Jaiswal/Quality/Plant/Torrent@TorrentPharma
Date: 18/08/2018 10:42 AM
Subject: Re: Fwd: Valsartan recall discussion needed

not sure about the PA however we will discussed and revert.
we have initiated this activity for domestic also.
currently hetro is supplier and there is possibility for such impurity. we are testing control samples and will conclude.

From: Samir/Corporate/Torrent Ltd
To: Jinesh Shah/Operations/Plant/Torrent@TorrentPharma
Cc: Sushil Jaiswal/Quality/Plant/Torrent@TorrentPharma
Date: 18-08-2018 10:36
Subject: Re: Fwd: Valsartan recall discussion needed

PA?

From: Samir/Corporate/Torrent Ltd
To: Jinesh Shah/Operations/Plant/Torrent@TorrentPharma
Cc: Sushil Jaiswal/Quality/Plant/Torrent@TorrentPharma
Date: 18/08/2018 10:35 AM
Subject: Re: Fwd: Valsartan recall discussion needed

how have we concluded that 15 batches need to be recalled and not 100?

From: Jinesh Shah/Operations/Plant/Torrent
To: Samir/Corporate/Torrent Ltd@TorrentPharma
Cc: Sushil Jaiswal/Quality/Plant/Torrent@TorrentPharma
Date: 18/08/2018 10:31 AM
Subject: Re: Fwd: Valsartan recall discussion needed

* initial fda/vendor indicated that there is issue with new ros of api.
* based on that we recalled 52 batchs from EU as they were with new ROS . no batches were supplied to US from new ros.

* vendor gave declaration to fda that there is issue wit new ros and old ros is ok (this declaration was based on chemistry).
* to check this method was under development at vendors end and the same was shared to us few days back.
*however w/o waiting from the same we initiated to develop the method at rnd (adl) and when we got the message on 26/6 procurement of impurities, etc was initiated for the same.
* it took 3 wks to develop the method. vendor shared their method 3 days back and it is still not workable.
* based on the testing of our method, we found that we will have to recall 15 batches (though fda has told us to recall only 5 batches).
* as of now there are 100 batches in market and we are doing the testing for all and if we found issues in all 100 batches or additional few more batches we will have to again voluntarily recall he same.
* we will concluding this analysis by end of next wk.

From: Samir/Corporate/Torrent Ltd
To: Jinesh Shah/Operations/Plant/Torrent@TorrentPharma
Cc: Sushil Jaiswal/Quality/Plant/Torrent@TorrentPharma
Date: 18-08-2018 10:11
Subject: Re: Fwd: Valsartan recall discussion needed

since 26.6,what action did we take to conclude if c batches had any issues or not?why could we not find it on our own that c batches also had issues rather than fda conveying it to us?

From: Jinesh Shah/Operations/Plant/Torrent
To: Samir/Corporate/Torrent Ltd@torrentpharma
Date: 17/08/2018 07:06 PM
Subject: Fwd: Valsartan recall discussion needed

Fyip

Begin forwarded message:

From: "Sushil Jaiswal" <SushilJaiswal@TorrentPharma.com>
Date: 17 August 2018 at 6:42:05 PM IST
To: "Dawn Chitty'" <dawnchitty@torrentpharma.us>, "Sue Perry" <susanperry@torrentpharma.us>, "Sanjay Gupta Torrent" <sanjaygupta@torrentpharma.us>, "Kalpesh T Patel" <KalpeshTPatel@torrentpharma.com>, "Maitrayee Mukherji" <MaitrayeeMukherji@torrentpharma.com>, "Suresh Shitole" <SureshShitole@torrentpharma.com>, "Jinesh Shah" <JineshShah@torrentpharma.com>
Subject: Fw: Valsartan recall discussion needed

In addition to below communication received from USFDA to recall 5 batches, we need to initiate recall of additional 11 batches based on the communication received today from Zhejiang Huahai Pharmaceutical co Ltd with the reason that analysis results provided by Vendor Zhejiang Huahai indicates higher level of NDMA impurities.

Finished product impacted :

Amlodipine and Valsartan Tablets, USP (5mg/320mg, and 10mg/320mg) and Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP (5mg/160mg/12.5mg, 5mg/160mg/25mg, 10mg/160mg/12.5mg, 10mg/160mg/25mg, 10mg/320mg/25mg)

Action Plan:

- Zhejiang Huahai has supplied analytical method for NDMA impurity which is not workable.
- API method developed by TRC ADL and impurity synthesized which was characterised for method development.
- Based on the result obtained from Zhejiang Huahai, ADL is analysing all 9 lots of API to countercheck results provided by Zhejiang Huahai .
- We are getting details from Zhejiang Huahai for possible reason for getting NDMA in C code of process as they have informed earlier that there is less chance of getting NDMA in C code of API.
- We are initiating recall notice and press release for recalling 16 batches impacted.

Additionally, we are analysing all 25 lots of API which were used in remaining 103 batches of formulation batches. Rest of the 26 formulation batches containing 5 lots of API were got expired. Based on outcome of results, we may need to initiate voluntary recall of impacted batches.

Background:

- We have received a notification from Valsartan API manufacturer- Zhejiang Huahai Pharmaceutical co Ltd. China On dated 26/06/2018 regarding Genotoxic impurity observed in valsartan API supplied by them.
- HUAHAI has informed that they are using two manufacturing process. These process is being control by code numbers 1) C5069- Old process and 2) D5191- New Process.
- Impact assessment carried out on 07 July 18 for US market and concluded that total 129 batches of formulation were manufactured using C code of API. There were no batches manufactured using D code of API for US market.
- On 13th July 18, ROS evaluation done by Zhejiang Huahai and COAs shared to USFDA along with details of 129 batches manufactured using C code of API.
- On 21st July 18, FDA asked total list of API batches vs formulation batches manufactured and status of formulation batches. (Total 48 batches were manufactured using D code of API supplied to different markets, which were recalled). Currently there are total 103 batches in the market which were manufactured using C code of API.

----- Forwarded by Kalpesh T Patel/Quality/TRC/Torrent on 17-08-2018 17:51 -----

From: Maitrayee Mukherji/Quality/TRC/Torrent
To: Kalpesh T Patel/Quality/TRC/Torrent@TorrentPharma, Brijesh H Patel/Quality/TRC/Torrent@TorrentPharma
Date: 17-08-2018 17:46
Subject: Fw: Valsartan recall discussion needed

fyr
Regards,

Maitrayee Mukherji
----- Forwarded by Maitrayee Mukherji/Quality/TRC/Torrent on 08/17/2018 05:46 PM -----

From: Dawn Chitty <dawnchitty@torrentpharma.us>
To: "SushilJaiswal@TorrentPharma.com" <SushilJaiswal@TorrentPharma.com>, "DeepaJoshi@torrentpharma.com" <DeepaJoshi@torrentpharma.com>
Cc: Arunesh Verma <arunverma@torrentpharma.us>, "AshishHajarnis@TorrentPharma.com" <AshishHajarnis@TorrentPharma.com>, "hardikvora@torrentpharma.com" <hardikvora@torrentpharma.com>, "JayatibhaChakrabarti@TorrentPharma.com" <JayatibhaChakrabarti@TorrentPharma.com>, jocelyn rivera <jocelynrivera@torrentpharma.us>, Joseph DelBuono <JosephDelBuono@torrentpharma.us>, "MaitrayeeMukherji@torrentpharma.com" <MaitrayeeMukherji@torrentpharma.com>, "ParasSheth@torrentpharma.com" <ParasSheth@torrentpharma.com>, "PurushottamSudele@torrentpharma.com" <PurushottamSudele@torrentpharma.com>, Sanjay Gupta <sanjaygupta@torrentpharma.us>, "SumitBasu@TorrentPharma.com" <SumitBasu@TorrentPharma.com>, Sue Perry <susanperry@torrentpharma.us>, "TriptiGandhi@torrentpharma.com" <TriptiGandhi@torrentpharma.com>, "VijayKPatel@TorrentPharma.com" <VijayKPatel@TorrentPharma.com>, "VinodSingh@torrentpharma.com" <VinodSingh@torrentpharma.com>
Date: 08/17/2018 03:57 AM
Subject: Valsartan recall discussion needed

Hi Sushil,

After discussion with FDA this afternoon, they have identified 3 batches of finished AVH (BBX2E001, BBX2E002, BBX2E003) that contained NDMA above allowable levels. This lot of API (C5069-15-039MMN) was also used in an additional 2 batches of finished goods (BBX2E004, BBX2E005). FDA communicated that they consider these batches adulterated. Please confirm this batch of API was only used in these 5 lots of finished goods.

I confirmed we would today notify customers who received these batches to quarantine the goods. We have also quarantined all valsartan containing goods stored at our warehouse this afternoon.

FDA has asked for our decision on what market action to take, as well as, draft recall letters and a draft press release within 24 hours.

FDA confirmed they tested the finished goods using their own developed method (GC-MS and GC-FID). They have agreed to share the method details but I have not received anything as of now.

I'm of the opinion we need to recall these 5 batches.

We need to discuss what to do with the remaining products. Please let me know when you are available to discuss this.

The draft documents are attached.

Deepa, I need you to please initiate the following as soon as possible:
1. We need a medical assessment of risk of the potential impurity. Also, look at the draft press release and see if you agree with the advice about not immediately stopping treatment.
2. Search the PV database for adverse events and/or product complaints associated with our valsartan containing products. Will need to comment on whether we've received cases we feel are related to this impurity.
3. Start a Q&A document for Apcer and one for Qualanex. Contact details for both companies are being provided publically. Qualanex is our return company that will be sending return materials and physically receiving the recalled product back to their facility.

Thanks,
Dawn[attachment "Press Release Aug 16.docx" deleted by Kalpesh T Patel/Quality/TRC/Torrent] [attachment "Recall Notice July 12.docx" deleted by Kalpesh T Patel/Quality/TRC/Torrent]